

**UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE**

AZURITY PHARMACEUTICALS, INC.,

*Plaintiff,*

v.

BIONPHARMA INC.,

*Defendant.*

C.A. No. 21-1286-LPS

C.A. No. 21-1455-LPS

**DEFENDANT BIONPHARMA'S MOTION  
TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(6)**

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<b>Abbreviation</b>	<b>Meaning</b>
'008 patent	U.S. Patent No. 9,669,008 B1 (21-1286 D.I. 9-3, 7/13/21 Shrestha Decl. Ex. C)
'023 patent	U.S. Patent No. 11,040,023 B2 (21-1286 D.I. 89-1, First Am. Compl. Ex. A)
'405 patent	U.S. Patent No. 11,141,405 B2 (21-1455 D.I. 1, Compl. Ex. A)
'442 patent	U.S. Patent No. 9,808,442 B2 (21-1286 D.I. 9-4), 7/13/21 Shrestha Decl. Ex. D)
'482 patent	U.S. Patent No. 10,786,482 B2 (21-1286 D.I. 9-12, 7/13/21 Shrestha Decl. Ex. L)
'621 patent	U.S. Patent No. 10,918,621 B2 (21-1286 D.I. 9-13, 7/13/21 Shrestha Decl. Ex. M)
'745 patent	U.S. Patent No. 10,039,745 B2 (21-1286 D.I. 9-5, 7/13/21 Shrestha Decl. Ex. E)
'868 patent	U.S. Patent No. 10,772,868 B2 (21-1286 D.I. 9-11, 7/13/21 Shrestha Decl. Ex. K)
'987 patent	U.S. Patent No. 10,154,987 B2 (21-1286 D.I. 9-6, 7/13/21 Shrestha Decl. Ex. F)
ANDA	Abbreviated New Drug Application pursuant to 21 U.S.C. § 355(j)
Azurity	Plaintiff Azurity Pharmaceuticals, Inc., successor-in-interest to Silvergate Pharmaceuticals, Inc.
Azurity's enalapril liquid patent family	'008, '442, '745, '987, '482, '868, '621, '023, and '405 patents
Azurity's TRO/PI Motion	21-1286 D.I. 24, Azurity's Motion for Order to Show Cause for Temporary Restraining Order, Preliminary Injunction, and Other Emergent Relief
Bionpharma	Defendant Bionpharma Inc.
Bionpharma's ANDA	Bionpharma's ANDA No. 212408
Bionpharma's First Motion	21-1286 D.I. 8, Defendant Bionpharma's Motion to Dismiss

<b>Abbreviation</b>	<b>Meaning</b>
to Dismiss or Bionpharma's First MTD	Pursuant to Fed. R. Civ. P. 12(b)(6)
Delaware CoreRx suit	<i>Azurity Pharm., Inc. v. CoreRx, Inc.</i> , C.A. No. 21-1522-LPS
First Amended Complaint	21-1286 D.I. 89, First Amended and Supplemental Complaint
First Wave Patents	'008, '442, '745, and '987 patents
First Wave Suits	<i>Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.</i> , C.A. Nos. 18-1962 and 19-1067 (D. Del.)
Florida CoreRx suit	<i>Azurity Pharm., Inc. v. CoreRx, Inc.</i> , No. 8:21-cv-2515 (M.D. Fla.)
MMSA	November 2020 Master Manufacturing Supply Agreement entered into between Bionpharma and CoreRx governing the commercial manufacture and supply of Bionpharma's ANDA product by CoreRx.
JSD	Joint Stipulation of Dismissal entered in the Second Wave Suits (20-1256 D.I. 106)
PI	Preliminary injunction
Second Wave Patents	'868, '482, and '621 patents
Second Wave Suit	<i>Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.</i> , C.A. No. 20-1256 (D. Del.)
7/13/21 Shrestha Declaration	21-1286 D.I. 9, July 13, 2021 Declaration of Roshan P. Shrestha, Ph.D.
Third Wave Suits	The instant actions, <i>Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.</i> , C.A. Nos. 21-1286-LPS, 21-1455-LPS (D. Del.)

Defendant Bionpharma respectfully submits the instant Brief in support of its Motion to Dismiss pursuant to Fed. R. Civ. P. 12(b)(6), which seeks dismissal of the First Amended and Supplemental Complaint (“First Amended Complaint”) filed in Civil Action No. 21-1286-LPS (21-1286 D.I. 89) and the Complaint filed in Civil Action No. 21-1455-LPS (21-1455 D.I. 1) (“Bionpharma’s Motion”).

### **INTRODUCTION**

Dismissal of the instant suits is warranted under the “two dismissal rule” of Fed. R. Civ. P. 41(a)(1)(B) and the doctrine of claim preclusion. Specifically, Plaintiff Azurity recently ***twice voluntarily dismissed*** the same causes of action asserted in the instant suits—alleged infringement of U.S. Patent Nos. 11,040,023 (“’023 patent”) and 11,141,405 (“’405 patent”) by Bionpharma’s 1 mg/mL enalapril maleate oral solution (“Bionpharma’s ANDA Product”) described in Bionpharma’s ANDA No. 212408 (“Bionpharma’s ANDA”)—that Azurity had filed against CoreRx, Inc. (“CoreRx”), the company that Bionpharma contracted with to develop Bionpharma’s ANDA product and that currently commercially manufactures Bionpharma’s ANDA product. As this Court has explained, by operation of law, the second of those two voluntary dismissals “serves as an ‘adjudication upon the merits’ and the doctrine of *res judicata* applies.” *St. Clair Intellectual Prop. Consultants, Inc. v. Samsung Elecs. Co.*, 291 F.R.D. 75, 77 (D. Del. 2013) (quoting FED. R. CIV. P. 41(a)(1)(B)). Because, as explained below, Bionpharma is indisputably in privity with CoreRx with respect to Bionpharma’s ANDA product and Azurity’s ’023 and ’405 patent infringement claims, the instant suits must be dismissed on claim preclusion grounds pursuant to Fed. R. Civ. P. 41(a)(1)(B).<sup>1</sup>

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<sup>1</sup> Although Bionpharma previously filed a motion to dismiss the Complaint filed in the 21-1286 action pursuant to Fed. R. Civ. P. 12(b)(6), *see* 21-1286 D.I. 8 (“Bionpharma’s First Motion to Dismiss” or “Bionpharma’s First MTD”), the instant successive motion to dismiss is permitted

### **NATURE AND STAGE OF THE PROCEEDINGS**

As this Court is aware, Bionpharma and Azurity have been litigating Bionpharma's ANDA product and Azurity's enalapril liquid patent family for over three years in this Court, starting with the First Wave Suits,<sup>2</sup> which went to final judgment in Bionpharma's favor and are now up on appeal;<sup>3</sup> continuing with the Second Wave Suit,<sup>4</sup> which was dismissed with prejudice (absent an appellate ruling eliminating collateral estoppel from the First Wave Suits);<sup>5</sup> and now continuing with the instant 21-1286-LPS and 21-1455-LPS actions ("Third Wave Suits"). In the instant Third Wave Suits, Azurity asserts that Bionpharma's ANDA product infringes two additional patents in Azurity's enalapril liquid patent family that recently issued—the '023 and '405 patents. *See* 21-1286 D.I. 89, First Am. Compl. ¶¶ 21-38 ('023 patent infringement claims); 21-1455 D.I. 1, Compl. ¶¶ 22-38 ('405 patent infringement claims).

#### **C.A. NO. 21-1286-LPS**

Azurity originally instituted the 21-1286 action in the District of New Jersey on June 22, 2021, as *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 21-12870 (D.N.J.) (21-1286 D.I. 1, Compl.), asserting that Bionpharma's ANDA product infringes the '023 patent (21-1286 D.I. 1, Compl.), but, on September 10, 2021, that court granted a § 1404(a) transfer motion

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because the grounds for the instant Motion were not available to Bionpharma when it filed its First Motion to Dismiss. *See* FED. R. CIV. P. 12(g)(2). As explained below, the suits Azurity filed against CoreRx were not dismissed until November 26, 2021, after Bionpharma's First Motion to Dismiss was filed and resolved.

<sup>2</sup> *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962-LPS and 19-1067-LPS (D. Del.).

<sup>3</sup> 18-1962 D.I. 270, Final J.; 18-1962 D.I. 271, Notice of Appeal.

<sup>4</sup> *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. No. 20-1256-LPS (D. Del.).

<sup>5</sup> 20-1256 D.I. 106, Joint Stipulation for Dismissal ("JSD").



Bionpharma filed (21-1286 D.I. 57), and the New Jersey suit was transferred here and assigned Civil Action No. 21-1286-LPS.

Prior to transfer, on July 14, 2021, Bionpharma filed its First Motion to Dismiss the original complaint on claim preclusion grounds based on the final judgment entered in the First Wave Suits, and based on the JSD entered in the Second Wave Suit. 21-1286 D.I. 8. Bionpharma secured final FDA approval of its ANDA on August 10, 2021, and launched its ANDA product on or about August 17, 2021. 21-1286 D.I. 89, First Am. Compl. ¶ 16. On August 19, 2021, Azurity moved for an order to show cause for temporary restraining order, preliminary injunction, and other emergent relief (21-1286 D.I. 24, “Azurity’s TRO/PI Motion”).

After transfer, on October 27, 2021, Azurity moved for leave to amend and supplement the Complaint with claims for actual infringement under 35 U.S.C. § 271(a)-(c) and damages. 21-1286 D.I. 73.

On November 10, 2021, after transfer, this Court held a hearing on Bionpharma’s First Motion to Dismiss and on Azurity’s TRO/PI Motion. The Court denied without prejudice Bionpharma’s First Motion to Dismiss, granting Bionpharma leave to re-file the motion at a later date. 21-1286 D.I. 87, Oral Order; 21-1286 D.I. 96, 11/10/21 Hr’g Tr. 115:11-17. The Court also denied Azurity’s TRO/PI motion, and ordered the parties to meet and confer regarding scheduling and to submit a proposed scheduling order by November 23, 2021.<sup>6</sup> 21-1286 D.I. 87-88.

### **C.A. NO. 21-1455-LPS**

Azurity instituted the 21-1455 suit on October 15, 2021, asserting that Bionpharma’s ANDA product infringes the ’405 patent. 21-1455 D.I. 1, Compl. On October 27, 2021, the

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<sup>6</sup> The Court subsequently extended that deadline to December 7, 2021. 21-1286 D.I. 95.

parties stipulated that the deadline for Bionpharma to answer, move, or otherwise respond to the Complaint would be two weeks from the date that the Court resolved Bionpharma's First Motion to Dismiss filed in the 21-1286 suit. 21-1455 D.I. 10. The parties thereafter stipulated to extend the deadline for Bionpharma to answer, move, or otherwise respond to the First Amended Complaint in the 21-1286 action and to the Complaint in the 21-1455 action until December 6, 2021. 21-1286 D.I. 94; 21-1455 D.I. 11. The instant Motion followed.

### **RELEVANT FACTUAL BACKGROUND**

As this Court found after trial in the First Wave Suits, Bionpharma contracted with CoreRx, a pharmaceutical contract development and manufacturing organization, to jointly develop Bionpharma's ANDA product. 18-1962 D.I. 257, Op. at 4, 8.<sup>7</sup> As explained above, Bionpharma launched its ANDA product on or about August 17, 2021. CoreRx commercially manufactures and supplies Bionpharma's ANDA product.

On October 26, 2021, Azurity instituted suit against CoreRx in the Middle District of Florida alleging that CoreRx's commercial manufacture and sale of Bionpharma's ANDA product infringes the '023 and '405 patents. Ex. A, *Azurity Pharm., Inc. v. CoreRx, Inc.*, No. 8:21-cv-2515 (M.D. Fla.) ("Florida CoreRx suit"), D.I. 1, Compl. (without attachments) ¶¶ 1, 3, 30-32, 33-57. The next day, October 27, 2021, Azurity filed a nearly duplicative suit against CoreRx in this Court. *See Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS ("Delaware CoreRx suit"), D.I. 1, Compl. Azurity identified the Delaware CoreRx Suit as

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<sup>7</sup> As this Court's opinion in the First Wave Suits and other published legal documents discussed herein are "matters of public record," this Court may take judicial notice of these documents in connection with the instant Motion. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d Cir. 1993); *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 526 (D. Del. 2014).

related to the First, Second, and Third Wave Suits against Bionpharma. 21-1522 D.I. 1-2, Civil Cover Sheet at Attached List.

On November 26, 2021, Azurity voluntarily dismissed both the Florida and Delaware CoreRx Suits. Ex. B, Florida CoreRx suit, D.I. 16, Notice of Dismissal without Prejudice; 21-1522 D.I. 6, Notice of Dismissal without Prejudice.

### **SUMMARY OF THE ARGUMENT**

Although Azurity's dismissals of the Florida and Delaware CoreRx suits are styled as "without prejudice," by operation of law, Azurity's dismissal of the second of those cases "serves as an 'adjudication upon the merits' and the doctrine of *res judicata* applies." *St. Clair*, 291 F.R.D. at 77 (quoting FED. R. CIV. P. 41(a)(1)(B)). Because, as explained below, Bionpharma and CoreRx are indisputably in privity with one another as to Bionpharma's ANDA product and Azurity's '023 and '405 patent infringement claims against that product, Azurity's infringement claims against Bionpharma in the instant Third Wave Suits are precluded as a matter of law, as they assert the same cause of action that that was, by operation of law, dismissed with prejudice when Azurity voluntarily dismissed the second of the Florida and Delaware CoreRx suits.

### **ARGUMENT**

#### **I. LEGAL STANDARD**

##### **A. Fed. R. Civ. P. 12(b)(6)**

In deciding a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), this Court is to "accept all factual allegations in the complaint as true, construe the complaint in the light favorable to the plaintiff, and ultimately determine whether plaintiff may be entitled to relief under any reasonable reading of the complaint." *Mayer v. Belichick*, 605 F.3d 223, 229 (3d Cir. 2010).

## B. Claim Preclusion

Claim preclusion is a question of law. *Brain Life, LLC v. Elekta Inc.*, 746 F.3d 1045, 1052 (Fed. Cir. 2014). Claim preclusion bars “the relitigation of a claim, or cause of action, or any possible defense to the cause of action which is ended by a judgment of the court.” *Id.* at 1053 (internal quotations omitted). “Under Third Circuit law . . . claim preclusion principles require: ‘(1) a final judgment on the merits in a prior suit involving[] (2) the same parties or their [privies]; and (3) a subsequent suit based on the same cause of action.’” *Senju Pharm. Co., Ltd. v. Apotex Inc.*, 746 F.3d 1344, 1348 (Fed. Cir. 2014) (quoting *CoreStates Bank, N.A. v. Huls Am., Inc.*, 176 F.3d 187, 194 (3d Cir. 1999) (square brackets in original)). “A dismissal with prejudice operates as an adjudication on the merits, so it ordinarily precludes future claims.” *Papera v. Pa. Quarried Bluestone Co.*, 948 F.3d 607, 611 (3d Cir. 2020) (citations and internal quotations omitted). Whether a cause of action in a patent case is the same as, or different from, another cause of action, is analyzed under Federal Circuit law. *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1165 (Fed. Cir. 2018). “[C]laim preclusion bars both claims that were brought as well as those that could have been brought.” *Brain*, 746 F.3d at 1053; *see also C.I.R. v. Sunnen*, 333 U.S. 591, 597 (1948).

“The defense of claim preclusion, . . . , may be raised and adjudicated on a motion to dismiss and the court can take notice of all facts necessary for the decision. . . . Specifically, a court may take judicial notice of the record from a previous court proceeding between the parties.” *Toscano v. Conn. Gen. Life Ins. Co.*, 288 F. App’x 36, at 38 (3d Cir. 2008); *see also Senju*, 746 F.3d at 1346 (dismissal based on claim preclusion affirmed on appeal).

## II. THE INSTANT THIRD WAVE SUITS MUST BE DISMISSED

Bionpharma's First Motion to Dismiss advanced a claim preclusion defense based on the final judgment and JSD entered in the First and Second Wave Suits, respectively. This Court denied Bionpharma's First Motion to Dismiss without prejudice (and expressly provided Bionpharma with leave to renew at a later date) because the Court was not prepared to rule at that instant that the claims of the '023 patent and the claims of the First and Second Wave Patents were "essentially the same" for claim preclusion purposes under the Federal Circuit's *SimpleAir* decision. 21-1286 D.I. 96, 11/10/21 Hr'g Tr. 114-115. That issue does not exist with respect to the instant Motion: the same patents asserted in the instant Third Wave Suits were asserted in the Florida and Delaware CoreRx Suits against that same accused activity, Bionpharma's ANDA product. The *only* possible perceived distinction between the instant Third Wave Suits and the Florida and Delaware CoreRx Suits is that Bionpharma is the defendant in the instant Third Wave Suits, while CoreRx, Bionpharma's contract manufacturer, was the defendant in the Florida and Delaware CoreRx Suits. However, as explained below, this is a distinction without a legal difference, as Bionpharma and CoreRx are indisputably in privity with one another as to Bionpharma's ANDA product and Azurity's '023 and '405 patent infringement claims. Dismissal on claim preclusion grounds of the instant Third Wave Suits is thus warranted.

### A. The "Two Dismissal Rule" Converts Azurity's Dismissal of the CoreRx Suits into an "Adjudication on the Merits"

As explained above, Azurity instituted the Florida and Delaware CoreRx suits on October 26 and 27, 2021, respectively, and then voluntarily dismissed both on November 26, 2021. Ex. B, Florida CoreRx suit, D.I. 16; 21-1522 D.I. 6. Azurity's voluntary dismissal of the second of the Florida and Delaware CoreRx suits on November 26, 2021 was an "adjudication on the

merits” by operation of law pursuant to Fed. R. Civ. P. 41(a)(1)(B), and therefore a dismissal with prejudice, irrespective of how Azurity styled the dismissal. *St. Clair*, 291 F.R.D. at 77; FED. R. CIV. P. 41(a)(1)(B). As this Court has observed, “[t]he two dismissal rule is designed to limit a plaintiff’s ability to dismiss an action and encourage[s] plaintiffs to diligently prepare their papers, to curb potential abuses of the judicial system.” *Id.*

Moreover, it matters not that the instant Third Wave Suits were already pending before the second of the Florida and Delaware CoreRx Suits was dismissed—that second dismissal still operates as an adjudication on the merits for purposes of the instant Third Wave Suits. *See Manning v. S.C. Dep’t of Highway and Pub. Transp.*, 914 F.2d 44, 47-48 (4th Cir. 1990) (affirming application of two dismissal rule where the second dismissal was filed after the third action was already pending); *Cabot Golf CL-PP v. Nixon Peabody, LLP*, 575 F. App’x 216, 218 (5th Cir.2014) (rejecting argument that “two dismissal rule” cannot apply to bar parallel/tandem litigation already pending before second dismissal); *see also Ferretti v. Beach Club Maui, Inc.*, Civ. No. 18-00012 JMS-RLP, 2018 WL 3078742, at \*4 (D. Haw. June 21, 2018) (same).

Finally, while Rule 41(a)(1)(B) does not expressly mention “privity,” as this Court has recognized, as long as Bionpharma is in privity, or has “some degree of relationship,” with CoreRx, Bionpharma may rely on Rule 41(a)(1)(B) in connection with a claim preclusion defense. *St. Clair*, 291 F.R.D. at 78; *see also Manning*, 914 F.2d at 47-48; *Sealy v. Branch Banking and Trust Co.*, 693 F. App’x 830, 834-35 (11th Cir. 2017); *Orman v. CitiMortgage*, C.A. No. 15-3432, 2016 WL 1592948, at \*4-5 (E.D. Pa. Apr. 21, 2016). As explained below, there can be no dispute that Bionpharma and CoreRx have the required degree of relationship and are in privity with one another as to Bionpharma’s ANDA product and Azurity’s ’023 and ’405 patent infringement claims.

## **B. Bionpharma and CoreRx Are in Privity**

As the Third Circuit has explained, “privity has traditionally been understood as referring to the existence of a substantive legal relationship, such as by contract, from which it was deemed appropriate to bind one [party] to the results of the other party’s participation in litigation.” *Nationwide Mut. Fire Ins. Co. v. George V. Hamilton, Inc.*, 571 F.3d 299, 310-11 (3d Cir. 2009). “Privity is defined as mutual or successive relationship to the same rights of property. . . . or such an identification of interest of one person with another as to represent the same legal right.” *Greenway Center, Inc. v. Essex Ins. Co.*, 475 F.3d 139, 149 (3d Cir. 2007) (internal quotations omitted); *see also Gambocz v. Yelencsics*, 468 F.2d 837, 841 (3d Cir. 1972) (“[R]es judicata may be invoked against a plaintiff who has previously asserted essentially the same claim against different defendants where there is a close or significant relationship between successive defendants.”). There can be no real dispute that Bionpharma and CoreRx—the company that Bionpharma contracted with to, in collaboration with Bionpharma, develop Bionpharma’s ANDA product, and who, pursuant to contract, commercially manufactures and supplies Bionpharma with its ANDA product—are in privity as to Bionpharma’s ANDA product and Azurity’s ’023 and ’405 patent infringement claims. “[A] lesser degree of privity is required” where, as here, “a new defendant [seeks] to benefit from claim preclusion than for a plaintiff to bind a new defendant in a later action.” *Lubrizol Corp. v. Exxon Corp.*, 929 F.2d 960, 966 (3d Cir. 1991).

As this Court found in connection with the First Wave Suits, Bionpharma contracted with CoreRx to assist in the development of Bionpharma’s ANDA product, and CoreRx did in fact assist in the development of Bionpharma’s ANDA product. 18-1962 D.I. 257, Op. at 4, 8. During the First Wave Suits, Azurity moved to compel Bionpharma to produce any agreements with CoreRx pertaining to the “research, development, promotion, manufacture, sale, offer for

sale, or importation of Bionpharma’s ANDA product.” 18-1962 D.I. 129, July 10, 2020 Hr’g Tr. 11:1-5, 44:6-12. This Court granted Azurity’s motion and ordered Bionpharma to produce such agreements, and Bionpharma complied with the Court’s order and produced such agreements.<sup>8</sup> *Id.* Furthermore, as Azurity admits through its allegations in the Florida and Delaware CoreRx suits, Bionpharma’s counsel also represented CoreRx in connection with third party discovery Azurity sought from CoreRx during the First Wave Suits. Ex. A, Florida CoreRx suit, D.I. 1, Compl. ¶ 22; 21-1522 D.I. 1, Compl. ¶ 21. Azurity also admits through its allegations in the Florida and Delaware CoreRx suits that CoreRx currently commercially manufactures and supplies Bionpharma’s ANDA product to Bionpharma. Ex. A, Florida CoreRx suit, D.I. 1, Compl. ¶¶ 1, 3, 30, 35, 48; 21-1522 D.I. 1, Compl. ¶¶ 1, 3, 4, 6, 19, 29, 34, 47.

Based on all of these indisputable facts, there can be no dispute that Bionpharma and CoreRx are in privity with respect to Bionpharma’s ANDA product and Azurity’s ’023 and ’405 patent infringement claims against that product. Bionpharma contracted with CoreRx to develop Bionpharma’s ANDA product, which CoreRx performed under, and Bionpharma and CoreRx currently have a contract in place for the manufacture and supply of Bionpharma’s ANDA product by CoreRx. Those contractual relationships by themselves are sufficient to establish privity between Bionpharma and CoreRx as to Bionpharma’s ANDA product. *Nationwide*, 571 F.3d at 310-11. Beyond the contractual relationships, CoreRx’s actual development and

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<sup>8</sup> On December 1, 2020, pursuant to the Court’s July 10, 2020 order, Bionpharma produced to Azurity the November 2020 Master Manufacturing Supply Agreement entered into between Bionpharma and CoreRx governing the commercial manufacture and supply of Bionpharma’s ANDA product by CoreRx (“MMSA”). That agreement includes an indemnity clause whereby Bionpharma agrees to indemnify CoreRx in connection with, *inter alia*, losses sustained by CoreRx in connection with intellectual property infringement claims brought by a third party against CoreRx in connection with the development and manufacture of Bionpharma’s ANDA product, which also supports finding of privity. *Trustees of Boston Univ. v. Kingbright Elec. Co.*, 427 F. Supp. 3d 246, 252 (D. Mass. 2019). At the Court’s request, Bionpharma will promptly submit the MMSA to the Court.



manufacture of the very ANDA product that Bionpharma has secured FDA approval to commercially market, and that Bionpharma does commercially market and sell right now, also supports a finding of privity between Bionpharma and CoreRx, as Bionpharma and CoreRx have “a mutual or successive relationship to the same rights of property,” namely, Bionpharma’s ANDA product. *Greenway*, 475 F.3d at 149 (internal quotations omitted); *see also Sam Ram Imports Inc. v. Meenakshi Overseas LLC*, C.A. No. 17-11872 (JLL), 2018 WL 2045996, at \*4 (D.N.J. May 1, 2018) (finding privity between overseas manufacturer and U.S. distributor of manufacturer’s product because of the manufacturer-distributor relationship and because “some contractual relationship must exist between [the distributor] and [the manufacturer] in order for [the distributor] to have any legal right in [the manufacturer’s product].”).

More importantly, Bionpharma and CoreRx share the same legal rights and relationship to the subject matter of the instant Third Wave Suits and the Delaware and Florida CoreRx suits. *See Manning*, 914 F.2d at 48; *St. Clair*, 291 F.R.D. at 78 (discussing *Manning*). There can be no dispute that a finding of infringement against Bionpharma in these cases would bind CoreRx on collateral estoppel grounds, and also that a finding of infringement against CoreRx in the Delaware or Florida CoreRx suits would have bound Bionpharma on collateral estoppel grounds. Conversely, there can be no dispute that a finding of non-infringement by this Court in the instant Third Wave Suits would inure to the benefit of CoreRx under collateral estoppel, and that Bionpharma would have been able to rely on a finding of non-infringement in the Florida and Delaware CoreRx Suits to raise a collateral estoppel defense in the instant Third Wave Suits. These indisputable considerations also support a finding of privity. *Nationwide*, 571 F.3d at 311 (“[Privity] is now used as a way to express the conclusion that nonparty preclusion [i.e. collateral estoppel] is appropriate on any ground.” (internal quotations omitted)).

Given the special relationship between Bionpharma and CoreRx pertaining to Bionpharma's ANDA product and Azurity's infringement claims—including the contractual relationship between Bionpharma and CoreRx, and including CoreRx's actual development, commercial manufacture, and supply of Bionpharma's ANDA product—Bionpharma and CoreRx are in privity with respect to Bionpharma's ANDA product and Azurity's infringement claims as a matter of law. *See Watson v. Mylan Pharm., Inc.*, Case No. 18-04137-CM-JPO, 2019 WL 3252745, at \*4-5 (D. Kan. July 18, 2019) (dismissing claims against contract generic drug manufacturer on claim preclusion grounds because contract generic drug manufacturer (Catalent) and generic drug company who secured favorable judgment in previous litigation (Mylan) were in privity).

### **C. Azurity Asserts the Same Cause of Action**

There can also be no dispute that Azurity asserts in the instant Third Wave Suits the same causes of action adjudicated on the merits (by operation of law) in the Florida and Delaware CoreRx Suits. In determining when a cause of action is the same for claim preclusion purposes, the Federal Circuit looks to “the transactional facts from which [a cause of action] arises, and the extent of the factual overlap.” *Senju*, 746 F.3d at 1349. In the instant Third Wave Suits, Azurity asserts the same patents it asserted in the Florida and Delaware CoreRx Suits (the '023 and '405 patents) against the same accused activity (Bionpharma's ANDA product). In the patent context, “[c]laim preclusion will generally apply when a patentee seeks to assert the same patent against the same party [or its privies] and the same subject matter.” *Id.*

#### **1. The Accused Product Is the Same**

“One of the areas of factual overlap that [the Federal Circuit] consider[s] in a patent case involving claim preclusion is the overlap of *the product or process* accused in the instant action with *the product or process* accused in the prior action.” *Id.* (emphasis in original). In an

ANDA case, “the ‘product’ is the drug described in the ANDA.” *Id.* at 1349-50. In the Florida and Delaware CoreRx Suits, Azurity alleged that Bionpharma’s ANDA product infringed the ’023 and ’405 patents. Ex. A, Florida CoreRx Suit, D.I. 1, Compl. ¶ 1; 21-1522 D.I. 1, Compl. ¶ 1. In the instant Third Wave Suits, Azurity, by its own admission, accuses the same product. Ex. A, Florida CoreRx Suit, D.I. 1, Compl. ¶ 21; 21-1522 D.I. 1, Compl. ¶¶ 6, 20. “Because the product in the [instant Third Wave Suits] completely overlaps with the product in the [Florida and Delaware CoreRx Suits], there is on that basis no new cause of action.” *Senju*, 746 F.3d at 1350.

## **2. The Asserted Patents Are the Same**

Finally, there can be no dispute that Azurity asserts the same patents in the instant Third Wave Suits that it asserted in the Florida and Delaware CoreRx suits: the ’023 and ’405 patents.

\* \* \*

Because instant Third Wave Suits involve the same patents and accused product that were involved in the Florida and Delaware CoreRx suits, Azurity asserts the same cause of action here that was adjudicated on the merits by operation of law in the Florida and Delaware CoreRx suits, and thus, the instant Third Wave Suits must be dismissed. “Claim preclusion will generally apply when a patentee seeks to assert the same patent against the same party [or its privies] and the same subject matter.” *Senju*, 746 F.3d at 1349.

## **CONCLUSION**

For the foregoing reasons, Bionpharma respectfully requests that this Court dismiss with prejudice the First Amended Complaint (D.I. 89) in the 21-1286 action and the Complaint (D.I. 1) in the 21-1455 action.

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